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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,107	01/26/2006	Don Griffin	2G02.1-150 1	9522

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GARDNER GROFF GREENWALD & VILLANUEVA. PC
2018 POWERS FERRY ROAD
SUITE 800
ATLANTA, GA 30339

EXAMINER

EASTWOOD, DAVID C

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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02/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/566,107	Applicant(s) GRIFFIN ET AL.	
	Examiner DAVID EASTWOOD	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Receipt is acknowledged of applicant's amendment/petition to revive filed 10/29/2009. Claim 21 has been canceled without prejudice. Claims 1-20 and 22-25 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 22 is rejected under 35 U.S.C. 101 because the claimed method of reducing the sensation of pain by a subject does not require a machine, does not impose a meaningful limit on the claims scope outside of a field of use limitation, does not involve more than insignificant extra-solution activity and does not particularly transform a particular article. *In re Bilski* 545 F.3d 943 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008)

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7-8, 10, 20, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (US 5951493) (here after Douglas).

Regarding claim 1-3, 7-8, 10 20, 22, and 25, Douglas discloses a lancing device (10) for collecting a sample of body fluid from a sampling site on the skin of a subject, said lancing device comprising an outer body housing (12) and a lancet (40), the lancet being movable between a first position within the outer body housing and a second position wherein at least a sharp tip portion of the lancet extends through an opening in the outer body housing (see state of lancet disclosed in figure 3), and wherein the opening in the outer body housing has a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes (lobes corresponding to notches denoted by numeral 80 see figure 7), the periphery of the opening is non-planar (Fig. 7), a raised rim (65a) around the opening, the lobes (tabs adjacent to slots 80) comprise teeth with sharp points (corner of tabs previously described), at least one outwardly-projecting, non-planar lobe (lobe portion in communication with slot 80) having a sharply-pointed distal tip (see beveled portion of surface 65a depicted in fig. 7), the opening has an inside dimension that is smaller than a corresponding outside dimension of the lancet, thereby preventing the lancet from becoming stuck in the opening (reduced inner portion of inner portion 66 which abuts outer rim of lancet 40 see fig. 3).

Regarding claim 20, Douglas discloses a method for acquiring an increased volume of analytic fluid from a sampling site, the method comprising the steps of providing a lancing device with an end cap (annular portion with distal surface 65a depicted in fig. 7) defining a non-circular opening (fig. 7), placing the lancing device

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against the skin so that the skin is in communication with the non-circular opening (C7 L40-50), applying sufficient pressure on the lancing device to cause tension upon the skin within the non-circular opening (C7 L40-50), triggering the lancing device (C6 L56-64) and continuing to apply pressure upon the skin with the lancing device while fluid is extracted from the sampling site (C7 L5-17).

Regarding claim 22 and 25, Douglas discloses a method of reducing the sensation of pain by a subject during a lancing procedure (via reduction of housing contact surface area C7 L40-50), said method comprising contacting a skin surface at or adjacent a sampling site with an irregular lobed contact surface (C7 L40-50), wherein the step of contacting a skin surface at or adjacent a sampling site with an irregular lobed contact surface comprises contacting the skin surface with at least one outwardly-projecting, non-planar lobe (tabs associated with slots 80 in fig. 7) having a sharply-pointed distal tip (see beveled edge 65a disclosed in fig. 7).

3. Claims 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Christine et al. (US 3922099)(hereafter Christine).

Regarding claim 11-18, Christine discloses an end cap (capable of being used) for a lancing device, said end cap comprising a first end for connection (32) to the lancing device, and a second end defining an opening (opening at the distal end depicted in embodiments of fig, 5,6,8) through which a sharp tip of a lancet can pass, the opening having a non-circular periphery comprising a plurality of inwardly and outwardly directed lobes (fig. 5-6ab), the periphery of the opening is non-planar, a

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raised rim around the opening (see distal end of tip disclosed in fig. 5), the opening is generally cross-shaped, comprising four lobes (fig. 6a), the opening is generally star-shaped, comprising five lobes (fig. 6), the lobes are smoothly-rounded (opening disclosed in fig 8), the lobes comprise teeth with sharp points and at least one outwardly-projecting, non-planar lobe having a sharply-pointed distal tip see embodiment depicted in figure 6b).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4-6 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (US 5951493) (hereafter Douglas) in view of Christine et al. (US 3922099)(hereafter Christine).

Regarding claim 4-6, 23 and 24, Douglas discloses the claimed invention except for the opening is generally cross-shaped through which a lancet tip passes, comprising four lobes, the opening is generally star-shaped, comprising five lobes, the lobes are smoothly-rounded. However, Christine discloses a generally cross-shaped opening through which a lancet tip can pass (fig. 6a), comprising four lobes, the opening is generally star-shaped (fig. 6), comprising five lobes, the lobes are smoothly-rounded (Fig. 8), at least one outwardly-projecting, non-planar lobe having a sharply-pointed distal tip (fig. 6b). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Douglas with the end cap as disclosed by Christine. Doing so would provide a plurality of interchangeable end-caps with different open aperture areas which would allow the user to alter the amount of skin surface area exposed to the aperture thus controlling the amount of pressure applied to the surface of the skin.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (US 5951493) (hereafter Douglas) in view of Chelak et al. (US 6558402)(hereafter Chelak).

Regarding claim 9, Douglas discloses the claimed invention except for at least a portion of the outer body housing near the opening comprises a transparent material. However, Chelak discloses a portion of the outer body housing near the opening comprises a transparent material (115) (C7 L54-62). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Douglas with

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the transparent material viewing window of Chelak. Doing so would provide a means to visually inspect the targeted site.

8. Claim 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Christine et al. (US 3922099)(hereafter Christine) in view of Chelak et al. (US 6558402)(hereafter Chelak).

Regarding claim 19, Christine discloses the claimed invention except for a transparent portion near the opening. However, Chelak discloses a portion of the end cap near the opening comprising a transparent material (115) (C7 L54-62). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Christine with the transparent material viewing window of Chelak. Doing so would provide a means to visually inspect the targeted site or other internal components.

Response to Arguments

9. Applicant's arguments filed 10/29/2009 have been fully considered but they are not persuasive. Regarding applicant's arguments directed to the rejection of claims 11-18 as anticipated by Christine et al. The examiner would like to point out that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In regards to applicants arguments directed to the rejection of Claims 1-8 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,951,493 to Douglas et al. in view of U.S. Patent No. 3,922,099 to Christine et al. Claim 15 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,922,099 to Christine et al. in view of U.S. Patent No. 5,951,493 to Douglas et al. Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,951,493 to Douglas et al. in view of U.S. Patent No. 3,922,099 to Christine et al., and further in view of U.S. Patent No. 6,558,402 to Chelak et al. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,922,099 to Christine et al. in view of U.S. Patent No. 5,951,493 to Douglas et al., and further in view of U.S. Patent No. 6,558,402 to Chelak et al. Claims 20 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,951,493 to Douglas et al. in view of U.S. Patent No. 3,922,099 to Christine et al., the Examiner notes that this argument is addressed by a new grounds of rejection as set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
1/18/10